

2. ADMINISTRATIVE INFORMATION

MAY 11 2004

2.1 510(k) Summary of Safety and Effectiveness

(1) Submitter: CRADLE TECHNOLOGY CORP

6F, No. 59, Tung-Hsing Road, Taipei, 110, Taiwan, ROC

Tel: 886-2-87682688 Fax: 886-2-87682588

[http:// www.cradle.com.tw](http://www.cradle.com.tw)

Contact: Dr. Jen, Ke-Min, REG # 9616345

No.58, Fu Chiun Street, Hsin Chu City, 300, Taiwan, ROC

Tel: 886-3-5208829 Fax: 886-3-5209783

e-mail: ceirs.jen@msa.hinet.net

(2) Device Name:

- Trade name: CRADLE HIPAX PACS
- Common name: Medical Image Integrate System
-

Device system, image processing, radiological**Device Description** Picture archiving and communications system.**Medical Specialty** Radiology**Product Code** LLZ**Regulation Number** 892.2050

(3) Predicate Device:

- DVVNET International Technology Co., Ltd.
- DVNET Mdv-PACS, **K031816**

(4) Device Description:

CRADLE HIPAX PACS consists of databank mainframe, file storage backup system, medical tomography interlink, job query, image diagnose and archive, and medical information integral linking modules and subsystems.

(5) Intended Use of Device:

The CRADLE HIPAX PACS device is intended for the manipulation, management, and display of medical images. It can manage and display images from different modalities and interfaces and can distribute those images to various workstation, image storage and printing devices using DICOM or similar standards.

Typical users of this software system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.

(6) Substantial Equivalence to Predicate Device:

According to the above discussion and information, the new device and the predicate device utilize the similar technologies and design aspects. The subject device is very similar and performs the same clinical function as the predicate device. The main distinguishing characteristic of the subject device is the different functional distribution among the PACS system. Furthermore, this difference raises no safety and effectiveness hazard. Hence, they are considered to be substantially equivalent.

(7) Safety:

Even though the functions are distributed among different servers between two products, whole functions can be executed in the same way for two systems. The new product hence raises no new safety or effectiveness hazard.

(8) Conclusion:

According to the above discussion and information, the new device and the predicate device utilize the similar technologies and design aspects. The subject device is very similar and performs the same clinical function as the predicate device. The main distinguishing characteristic of the subject device is the different functional distribution among the PACS system. Furthermore, this difference raises no safety and effectiveness hazard. Hence, they are considered to be substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2004

Cradle Technology Corp.
% Dr. Jen, Ke-Min
ROC Chinese-European
Industrial Research Society
No. 58, Fu-Chiun St.,
HSIN-CHU CITY, 300
CHINA (TAIWAN)

Re: K033912
Trade/Device Name: Cradle Hipax PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: March 17, 2004
Received: March 22, 2004

Dear Dr. Jen, Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

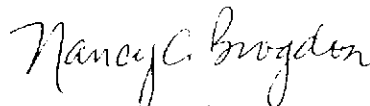
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033912

2.2 FDA Indication for Use Form :

Applicant : CRADLE TECHNOLOGY CORP.

510(k) Number : TO BE ASSIGNED

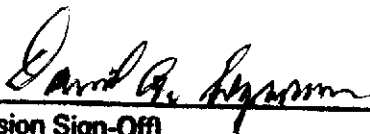
Device Name : CRADLE HIPAX PACS

Indications for Use :

- The CRADLE HIPAX PACS device is intended for the manipulation, management, and display of medical images. It can manage and display images from different modalities and interfaces and can distribute those images to various workstation, image storage and printing devices using DICOM or similar standards. Typical users of this software system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033912

Prescription Use ✓

OR

Over-The-Counter

Per 21 CFR 801.109

(Optional Format 1-2-96)